european biopharmaceutical enterprises

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON PUBLIC PROCUREMENT COM (2011) 896

EBE POSITION PAPER ON TENDERING OF BIOSIMILARS/BIOLOGICALS

European Biopharmaceutical Enterprises (EBE) is the Brussels-based European trade association that represents biopharmaceutical companies of all sizes operating in Europe. It has 65 member companies, which are engaged in the research, development, manufacturing and marketing of new medicinal products using biotechnology. EBE also operates as the biotechnology arm of EFPIA, the European pharmaceutical industry federation.

Tenders and Biological Medicines

Tenders are used where multiple suppliers bid to provide products that are deemed to be interchangeable[1]. Due to their unique starting material and the complex manufacturing process, biological medicines, including biosimilars, should not be subject to automatic substitution.[2] Procurement practices such as tendering should therefore be limited to pharmaceutical products that are interchangeable and always provide for a sufficiently broad choice of products.

Background

Nearly all EU countries have tender and negotiation mechanisms in the hospital sector in place.[3] This procurement practice can be defined as "buying pharmaceuticals by purchasers like public hospital associations on the basis of a –often strictly defined-tendering procedure with granting the contract to a pharmaceutical company/importer who offered the best bid."[4] This practice is primarily used for medicines which are genuinely identical, bio-equivalent, multi-sourced and off-patent, i.e., small chemical molecules, so-called generics and their originators that have lost patent and exclusivity.

---

[1] EFPIA response to the Green Paper on the modernisation of EU public procurement policy - Towards a more efficient European procurement market COM(2011)15 final – Commission register ID Nr 38526121292-88.

[2] EBE (2011), EBE position paper. Recommendations on the use of biological medicines products: substitution and related healthcare policies. The full paper can be accessed under: www.ebe-biopharma.org; see also Directive 2004/27/EC, Recital 15: "Biological medicinal products similar to a reference medicinal product do not usually meet all the conditions to be considered as a generic medicinal product (…)."

[3] Sabine Vogler (2011), Pricing and Reimbursement of Pharmaceuticals. A European Overview; WHO Collaboration Centre, Presentation given at the PPRI 2011 conference; www.whocc.goeg.at. All countries have tender and negotiations in the hospital sector, 7 countries have mainly tenders.

[4] Leopold C, Habl C, Vogler S. (2008), Tendering of pharmaceuticals in EU member states and EEA countries. Results from the country survey. Vienna: ÖBIG Forschungs-und Planungsgesellschaft mbH.

However, the same criteria can obviously not be applied when selecting and purchasing non-identical medicines. Due to the differences of these medicines this procurement practice bears the risk that patients do not obtain the medicine best suited to treat their conditions. Moreover, in the case of single-source, i.e. patented medicines, rewards for innovation would be undermined.

As for biological medicines, tendering of biosimilars and/or their originators that have lost patent and exclusivity (in the following called "reference products") requires the same considerations. According to the European Medicines Agency (EMA) biosimilars are "not generic medicinal products, since it could be expected that there may be subtle differences between similar biological medicinal products from different manufacturers or compared with reference products".[5] Biosimilars applicants need to demonstrate similarity to the reference product; assessments of interchangeability and substitutability are neither part of the scientific evaluation nor a condition to gain marketing authorization. Therefore, no conclusion on interchangeability or automatic substitution can be made based on the grant of a market authorization.[6] With regard to biologicals individual patients may respond differently to the same treatment because of (genetic or environmentally determined) differences between patients, i.e. the so-called "inter-patient variability".

In general, a tender with biologicals - whether it includes one or several reference products and their corresponding biosimilar(s) -, where "one winner takes all" neglects these differences and can result in the forced switching of a broad patient population from their currently prescribed medication to the single biological from the winning tender.[7] In contrast, if a prescriber decides to switch a patient from an originator biological to a biosimilar, or vice versa, or from one biosimilar to another, he or she should

[5] See EMA (2006), Guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues; http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003920.pdf (accessed: 1st February 2012). This should not be confused with "biosimilar clones", ie., biosimilar drugs that are the same and differ only in the brand name. The German Pharmacists Association and the Sick Funds association recently announced an agreement to permit pharmacists to dispense any brand of biosimilars, which have identical manufacturing processes and are developed from the same cell line. Since it is the same molecule this policy does not pose any unintended consequences with switching.

[6] In order to be able to declare two products interchangeable, EBE believes that there needs to be reassurance that repeated switching between these two products will not pose additional risk of changes in efficacy and safety for patients, i.e. that any of the products declared interchangeable has the ability to produce the same results in any given patient over time. See EBE (2011), EBE position paper. Recommendations on the use of biological medicines products: substitution and related healthcare policies, p. 3. The full paper can be accessed under: www.ebe-biopharma.org

[7] I.e. Therefore there should be separate bids for different products and contracts should be separate for different products

inform and prepare the patient for use of the new product, which may have a different device and/or a different patient support system.[8] In case of any problems, the prescriber should be able to identify immediately the source of the problem, report it, and move to a better choice for the patient.

EBE's Position on Tendering

EBE recognises the role of public procurement processes, i.e. "to ensure the best possible procurement outcomes in terms of value for money."[9] Nevertheless procurement practices need to fit the purpose and therefore be in the interest of the patients including safety of the patient. In addition, as the proposal of the Public Procurement Directive states they should allow procurers to make better use of public procurement to support and promote innovation.

In the view of EBE, procurement practices such as tendering should always:

- Contain a variety of selection criteria and not only price;
- provide for a sufficiently broad choice of products, i.e., instead of a single medicine a variety of biological medicines should be available for patients;
- include a scientific committee, i.e. physicians, in the decision-making process, and should respect and safeguard the autonomy of clinical choice;
- allow continuation of treatment, i.e. any switching of treatment should only happen under the guidance of a treating physician in relation to the concerned patient.

For information please contact:

Christine Pätzold
Government and Public Affairs Relations

EBE-Biopharmaceutical Enterprises (EBE)
Tel: +32 2 626 25 62
Mob: +32 477 77 84 58

christinepatzold@ebe-biopharma.org
www.ebe-biopharma.org

[8] See Swedish Medical Products Agency (2011), Investigation of the possibility to extend the substitution system and of substitution for new prescriptions, p. 16

[9] COM(2011) 896 final, "Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on public procurement"